

REMARKS

I. Introduction

Receipt of an Office Action dated November 23, 2009 is acknowledged. In the Action, the claims are rejected as obvious over Treon *et al.*, *Semin. Oncol.* 2000, 27(5): 598-613 ("Treon"), in view of Ohtomo *et al.*, *Biochem, Biophys. Res. Comm.*, 1999, 258:583-591, Chiriva-Internati *et al.*, *Cancer Gene Therapy*, 2001, 8:S27 ("Chiriva-Internati ") (claims 1, 12 and 25), and further in view of WO 2001177362, as evidenced by Porgador *et al.*, *J. Exp. Med.*, 1995, 182:255-260 ("Porgador") (claims 1, 3, 12, 23 and 25), and further in view of Thurner *et al.*, *J. Exp. Med.* 1999, 190(11):1669-1678 ("Thurner") (claims 1, 3, 12, 23, 25 and 32).

II. Status of the Claims

In this Response, claims 1 and 32 are amended, and claim 3 is canceled. Support for this amended can be found throughout the specification and in the originally filed claim 2 and paragraph [0037] of the published application in particular. Upon entry of this amendment, claims 1, 12, 23, 25 and 32 will be under examination.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

III. Rejection of the Claims Under 35 U.S.C. § 103

Claims 1, 12 and 25 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over Treon, in view of Ohtomo and Chiriva-Internati. Claims 1, 3, 12, 23 and 25 are also rejected under 35 U.S.C. § 103 as being unpatentable over Treon, in view of Ohtomo and Chiriva-Internati., further in view of WO 2001177362, as evidenced by Porgador. Lastly, claims 1, 3, 12, 23, 25 and 32 are rejected under 35 U.S.C. § 103 as allegedly obvious over Treon, in view of Ohtomo and Chiriva-Internati., further in view of WO 2001177362, as evidenced by Porgador, and further in view of Thurner.

In particular, the claims are rejected because Chiriva-Internati “have demonstrated that HM1.24 antigen expressed by the viral vector and presented by the dendritic cells are capable of inducing significant cytotoxic T cell response” and it would have been obvious to pulse dendritic cells directly with HM1.24 antigen “in view of the teaching of Treon et al. that dendritic cells can be pulsed with whole tumor antigen, naked DNA or whole tumor RNA for treating multiple myeloma (MM).” Office Action at 3-4. Applicants respectfully disagree.

In the Chiriva-Internati reference, a viral vector comprising a HM1.24 *gene* was pulsed into dendritic cells. In this reference, a *soluble* HM1.24 *protein/peptide* was not pulsed. In addition, the Chiriva reference describes that “improvement in T-cell priming by DC, giving continuous protein expression, as most proteins have short half-lives.” This description teaches that for introduction of a protein into dendritic cells, the protein must continuously be expressed by introducing HM1.24 gene-containing viral vector into dendritic cells because the half-life of the protein is very short. Accordingly, Chiriva-Internati destroys the motivation for pulsing a *soluble* HM1.24 *protein/peptide* into dendritic cells. Also, Chiriva-Internati does not describe or suggest pulsing dendritic cells with a soluble HM1.24 protein/peptide using a viral vector.

Treon describes treatment of plasma tumor cells, such as multiple myeloma, by immunotherapy using dendritic cells pulsed with *whole tumor antigen, naked DNA or whole tumor RNA* . . . The description suggest the use of full length cancer antigen, tumor RNA but it does not suggest use of a part of a cancer antigen, tumor RNA, etc.

Additionally, Treon, on page 602, left column, upper paragraph, describes that “[a] soluble form of HM1.24 has not yet been detected.” Also, in the Office Action dated June 19, 2007, on page 9, lines 4 to 5, the Examiner stated that “Treon et al., do not specifically describe dendritic cells pulsed with HM 1.24 protein of HM1.24 peptide.” Thus, the Treon reference does not describe or suggest the use of dendritic cells pulsed with a soluble HM1.24 protein/peptide.

Although the Treon reference refers to a HM1.24 antigen, the description relates to the usefulness of an anti-HM1.24 antibody, and does not suggest pulsing dendritic cells with HM1.24 protein or HM1.24 peptide.

WO 2001/77362 describes only that a soluble HM1.24 protein can be used for *immunoassay* and does not suggest the use of a soluble HM1.24 peptide for *immunotherapy* using a T cell response. Accordingly, a person of ordinary skill in the art reading the above mentioned cited references, may consider that a vaccine comprising dendritic cells pulsed with a partial peptide rather than a full length peptide is not effective, and may also not have been motivated to construct a vaccine by pulsing a partial (soluble) HM1.24 peptide.

The deficiencies in the prior art teachings, however, are not made up for by the teachings in Ohtomo, Porgador, or Thurner. For example, Ohtomo describes that an HM1.24 antigen is a promising target for antibody-based immunotherapy of multiple myeloma. But does not suggest at all *immunotherapy using T cell reaction*, of which the mechanism is completely different from that of immunotherapy using antibody reaction. Similarly, Porgador fails to disclose dendritic cells pulsed by idiotypic vaccination using the soluble HM1.24 protein or HM1.24 peptide. And Thurner does not provide these teachings either.

Additionally, as can be seen from the result of Example 1 of the present invention, the vaccine of the present invention strongly responds to not only PBMCs loaded with HM1.24, but also autologous tumor cells expressing HM1.24. This is a remarkable and surprising effect.

Note that a soluble HM1.24 protein/peptide is shown as SEQ ID NO: 16 of the present application and is a part of the full length HM1.24, but has the N terminal portion deleted.

Because the clear deficiencies in the teachings in the combination of Treon and Chiriva-Internati are not made up for based on the teachings of Ohtomo, or Ohtomo, WO 200177362, and Porgador, or Ohtomo, WO 200177362, Porgador, and Thurner, the presently claimed invention is not obvious over the prior art. Therefore, for at least these reasons, Applicants respectfully request these rejections be withdrawn.

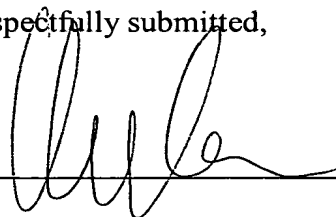
CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

By  VLM 55600

for Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

Date February 23, 2010

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399